

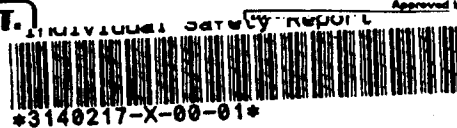
# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL

McNEIL CONSUMER PRODUCTS  
FORT WASHINGTON

Page \_\_\_\_ of \_\_\_\_



FDA Use only

<b>A. Patient information</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:15%;">1. Patient Identifier  In confidence</td> <td style="width:20%;">2. Age at time of event: unknown or Date of birth:</td> <td style="width:15%;">3. Sex (X) female ( ) male</td> <td style="width:15%;">4. Weight unk lbs or kgs</td> </tr> </table>				1. Patient Identifier  In confidence	2. Age at time of event: unknown or Date of birth:	3. Sex (X) female ( ) male	4. Weight unk lbs or kgs	<b>C. Suspect medication(s)</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td colspan="2">1. Name (give labeled strength &amp; mfr/labeler, if known)</td> </tr> <tr> <td colspan="2">#1 TYLENOL Analgesic Unknown</td> </tr> <tr> <td colspan="2">#2</td> </tr> <tr> <td>2. Dose, frequency &amp; route used</td> <td>3. Therapy dates (if unknown, give duration from/to (or best estimate))</td> </tr> <tr> <td>#1 unknown dose, po</td> <td>#1 unknown</td> </tr> <tr> <td>#2</td> <td>#2</td> </tr> <tr> <td colspan="2">4. Diagnosis for use (indication)</td> </tr> <tr> <td colspan="2">#1 unknown</td> </tr> <tr> <td colspan="2">#2</td> </tr> <tr> <td>6. Lot # (if known)</td> <td>7. Exp. date (if known)</td> </tr> <tr> <td>#1 Unknown</td> <td>#1 Unknown</td> </tr> <tr> <td>#2</td> <td>#2</td> </tr> <tr> <td colspan="2">9. NDC # - for product problems only (if known)</td> </tr> <tr> <td colspan="2">-</td> </tr> <tr> <td colspan="2">10. Concomitant medical products and therapy dates (exclude treatment of event) unknown</td> </tr> </table>				1. Name (give labeled strength & mfr/labeler, if known)		#1 TYLENOL Analgesic Unknown		#2		2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from/to (or best estimate))	#1 unknown dose, po	#1 unknown	#2	#2	4. Diagnosis for use (indication)		#1 unknown		#2		6. Lot # (if known)	7. Exp. date (if known)	#1 Unknown	#1 Unknown	#2	#2	9. NDC # - for product problems only (if known)		-		10. Concomitant medical products and therapy dates (exclude treatment of event) unknown																																																																	
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Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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